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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/817,704	08/25/1997	ANTHONIUS J. SWAAK	P8214-7002	8580

7590 12/16/2005

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EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/817,704	SWAAK, ANTHONIUS J.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,20,23-26,31 and 34-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,20,23-26,31 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 18, 20, 23-26, 31, and 34-36 are currently pending in this application.

2. Applicant's amendment, remarks, and declaration of Alan J. Howarth, Ph.D., filed 2/09/05 are acknowledged. Upon reconsideration and in view of the instant declaration, the original "Use" type claims are considered to comprise adequate written support for amended claims reciting a method of treatment. This finding in itself, however, does not mean that all now-claimed limitations find adequate support in the specification or claims as filed. Accordingly, the rejections set forth below remain.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 18, 20, 23-26, 31, and 34-36 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method of treating consisting of identifying a patient (now an RA patient), administering Epo to said patient, and identifying that said patient that suffers from morning stiffness, loss of grip strength, painful joints, or swollen joints has a lower level of morning stiffness, loss of grip strength, painful joints, or swollen joints after treatment.

B) a method of ameliorating an erythrocyte sedimentation rate or C-reactive protein level consisting of identifying a patient (now an RA patient), administering Epo to said patient, and identifying that said patient has an ameliorated erythrocyte sedimentation rate or C-reactive protein level.

A review of the specification discloses that the new limitations are found only in a specific example in the context of treating ACD patients (i.e., a specific subset of RA patients) with a specific dosage of Epo, for a specific timeframe, and not in the broad context of the instant claims.

Applicant's arguments, filed 9/07/05 have been fully considered but they are not persuasive. Applicant argues that one of ordinary skill in the art would understand the disclosed methods of treatment would be applicable to the treatment of all rheumatoid arthritis patients and further cites the declaration of Dr. Howarth.

It is unclear how Applicant finds support for this assertion in the instant specification. The specification does not disclose the Experimental section as merely exemplary nor even a preferred (but not limiting) embodiment. The specification discloses that "This study focused on the effects of r-hu-Epo on RA disease activity parameters. It is a part of a project studying the pathogenesis of ACD and possible therapeutic strategies. The effect of r-hu-Epo on the anaemia and iron metabolism is reported in more detail (21).

Ten patients with RA (22) were studied, fulfilling the criteria for ACD as proposed by Cartwright (8). ACD was confirmed by measuring stainable iron in a bone marrow preparation…".

The specification goes on to describe the selection criteria of a specific subset of ACD patients for treatment. Clearly then this method of the specification applies only to a limited ACD subset of RA patients, and then only with recombinant human Epo. Applicant's argument would seem to be that it would be obvious to apply the method to all RA patients (as is claimed). It is well-established, however, that obviousness is not the standard for a finding of adequate written description.

Applicant argues that the various claimed steps, e.g., identifying patients suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints is supported by the Treatment section of the specification starting at page 6.

Contrary to Applicant's assertions, the specification makes clear that patients were *not* selected/identified due to suffering from morning stiffness, loss of grip strength, painful joints, or swollen joints. Indeed, the specification specifically discloses that the patients were selected/identified employing ACD criteria as set forth above. Again, while certain method steps might be obvious, obviousness is not the standard for a finding of adequate written description. And again, there is no disclosure in the specification of identifying or measuring painful joints.

Further note that the method of the Experimental employs recombinant human Epo. Thus, the human Epo of Claims 23 and 25, which encompasses natural human Epo, comprises a limitation not disclosed in the specification in the claimed context. Likewise, the recombinant Epo of Claims 24 and 26 encompasses Epo from non-human species, again, a limitation not disclosed in the specification in the claimed context.

Also note that Applicant appears to admit that the ESR of the specification is limited to that measured by the Westergen method, yet this limitation is not recited in the claims.

7. No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

10. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Additionally, the Technology Center receptionist can be reached at (571) 272-1600.

12/13/05

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